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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,048	08/04/2003	Jallal Messadek	31927-CIP2	6961

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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/635,048	MESSADEK, JALLAL	
	Examiner	Art Unit	
	Timothy E. Betton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 31-41* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-25 and 27-30* is/are rejected.

7)☐ Claim(s) *14-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse in the reply filed on 6 April 2006 is acknowledged. The traversal is on the ground(s) that applicant notes that all of the elected claims are drawn to a controlled release pharmaceutical system, per se, and are not limited to a specific effect or treatment. Thus, given the election of Group V by this submission, it is believed by applicant that the requirement for further election of species is either not applicable to the Group V elected claims, or inappropriate as the controlled release pharmaceutical system as claimed is directed to the composition rather than only one result of several obtainable by the dosage form.

Applicant's traverse is acknowledged, however is not found persuasive because of applicant's election of Group V. Group V is drawn to a controlled release pharmaceutical system for delivering a compound in a time-controlled manner. The disclosure of a compound is drawn to a claimed pharmaceutical antithrombic combination in claims 1-7 and 33-37. Instant claims constitute Group I of the species election because of such a variance of factors with various compounds and combinations thereof. Therefore, a multiplicity of results is possible, for the several methods of use that are attainable.

Status of the Claims

Applicant's election with traverse in the reply filed on 6 April 2006 is acknowledged .The traversal is on the ground(s) that the election of Group V is principally drawn to a controlled release pharmaceutical system and not to the compound that it is designed to use.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-30 are currently pending for prosecution on the merits. Claims 1-13 and 31-41 have been withdrawn.

Information Disclosure Statement

The enclosed form 1449 under Other Documents heading discloses an entry directed toward a Naproxen monography, however there is no publication date cited. Therefore, it has been removed from consideration until the required correction is submitted by Applicant.

Objection

The claims are objected to because the lines are crowded too closely together, making reading difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

Claim Rejection-35 USC§ 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 29 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In instant claim 29, it discloses "for between about 240 minutes and 2160 minutes." In particular, the phrase "between about" is a vague and indefinite due to a conflict between whether "between" or "about" controls the metes and bounds of the

parameter modified therewith. Further, for the reasons listed above the term "about" again defines a broadness, which does not further limit what is the intended invention.

Claim Rejection-35 USC§ 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-25 and 27-30 are rejected under 35 U.S.C. 103(a) as being obvious and therefore unpatentable over Cubicciotti, R. (USPN 6287765 and PGPUB US 20020334757) in view of Malamud et al. (USPN 5928195), Murphy et al. (USPN 6399785), and Amarasinghe et al. (USPN 6355166)

The applied references have a common claimed invention and/or method steps with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130

stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are drawn to a controlled release pharmaceutical system suitable for delivering after administration in a time-controlled manner to the bloodstream of a mammal, comprising an effective amount of an active compound selected from the group consisting of a compound of disclosed formula [glycine betaine], or a pharmaceutically acceptable salt thereof; precursors thereof, and mixtures thereof.

Cubicciotti et al. teach multimolecular devices and drug delivery systems prepared from synthetic heteropolymers, heteropolymeric discrete structures, multivalent heteropolymeric hybrid structures, aptameric multimolecular devices, multivalent imprints, tethered specific recognition devices, paired specific recognition devices, nonaptameric multimolecular devices and immobilized multimolecular structures are provided, including molecular adsorbents and multimolecular adherents, adhesives, transducers, switches, sensors and delivery systems. Methods for selecting single synthetic nucleotides, shape-specific probes and specifically attractive surfaces for use in these multimolecular devices are also provided. In addition, paired nucleotide-nonnucleotide mapping libraries for transposition of selected populations of selected

nonoligonucleotide molecules into selected populations of replicatable nucleotide sequences are described. Further Cubicciotti et al. teach controlled release pharmaceutical system suitable to delivering (Abstract, column 38, lines 8-37) [...] to bloodstream (column 147, line 60), comprising an effective amount of an active compound or derivative thereof (column 183, line 61).

Instant claim 15 is obvious over Cubicciotti et al. in regard to oral and transdermal controlled release devices/preparations. Referenced patent discloses a time-controlled transdermal application (column 50, line 57) and time-controlled oral application (column 107, line 41).

Instant claim 17 is obvious over Cubicciotti et al. in regard to the disclosure: electronic element selected from the group consisting of an electronic device or/and chip. Referenced patent discloses numerous disclosures of chips and derivatives thereof (column 4,line 2; column 13, line 60; column 59, line 7).

Instant claim 19 is obvious over above- referenced PGPUB US 20020034757 A1 in regard to treating a condition, reducing the incidence, or reducing the severity of a condition, whereby said condition is blood flow disturbances, thrombosis, thromboembolic disorders. Referenced PGPUB discloses vascular thrombotic events and thrombosis (Section [808]).

Cubicciotti et al. does not teach the use with glycine betaine or any betaine derivative thereof. However, the Examiner refers to Malamud et al., which teach use with betaine or a betaine derivative and glycine derivative (column 5, lines 38 and 45, respectively) in a remotely controlled drug delivery device, which administers a dose of

said drug, agent or microbicide using a gas pressure delivery system. The device stores multiple doses of the drug or agent. A toroid shaped housing includes three chambers, a gas chamber containing a pressurized gas, a drug storage chamber containing the drug or agent, and an expandable chamber for delivering the drug from the drug storage. The device includes an electronic controller for opening a valve connecting the gas chamber to the expandable chamber for a predetermined period of time in order to deliver a predetermined dose of the drug. The controller communicates with a remote control device via radio frequency. The remote control device sends a signal to the controller, which causes a dose to be delivered. The controller returns a signal to the remote control device indicating that the dose has been delivered and a signal indicating when the device needs to be removed for maintenance. The device may be used in any body cavity to deliver any desired type of drug. Specifically in subject claim 8 and column 5, line 37 of instant patent, there is the direct disclosure of a derivative of betaine for use in controlled drug delivery device.

Malamud et al., does not teach the identical specifications of the electronic element as disclosed in instant claims but does disclose a form of gas pressure delivery system.

Malamud et al. further makes obvious the motivation to combine the use of betaine and derivatives thereof for use in a pharmaceutical delivery system. The motivation is further made obvious by references in view of Murphy et al. (USPN 6399785).

In view of Murphy et al. (USPN 6399785), the patented reference teaches the use of a pharmaceutical delivery system and glycine and/ or derivatives by referenced disclosure: the controlled release of active drug substances into the gastrointestinal, circulatory, lymphatic, cerebrospinal, synovial fluid, biliary, within the aqueous of the eye, or in other systems in the body of a [mammal] effected in a continuous and constant manner. (column 28, lines 1-18).

Further, claims 23-25, 27, and 28 are rejected under 35 USC 103(a) as being obvious over Cubicciotti et al. in view of Malamud et al.

Malamud et al. teaches an intravaginal microbicide device which is administered by way of a gas pressure delivery system. The device includes an electronic chamber for opening a valve connecting the gas chamber to the expandable chamber for a predetermined period of time in order to deliver a predetermined dose of the drug. The controller communicates with a remote control device via radio frequency. Referenced patent teaches that the dispersion time may vary depending on the drug used and the location of the drug delivery device 12. In the preferred embodiment, it is preferred that a delivered dose of the drug remains effective for at least six to eight hours [...] (column 5, lines 53-57).

Instant claims disclose a system adapted for controlling the release of an effective amount of a compound for at least ranges comprising at least 180 minutes to 360 minutes. The teaching of Malamud et al. of at least six to eight hours encompasses the ranges of the subject claims. The delivery/ dispersion methods are not identical, however, a common system of interval-based administration is practiced. The disclosed

ranges of instant claims disclose specific values in regard to the related, however, general teaching drawn to a predetermined period of time in the referenced patent.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the devices of Cubicciotti et al. and Murphy et al. and combine with Malamud et al. to include the administration of glycine betaine in a pharmacy delivery system. Glycine Betaine is notable for being site specific and of low toxicity in the prevention of thromboembolic events (Messadek USPN 6855734, column 5, lines 30 to 63). Therefore, a controlled-release pharmaceutical system incorporating glycine betaine and derivatives thereof would be apparent to combine to one of ordinary skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H. Marschel 12/18/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

TEB